

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

PA 78516 MBE

- 6 DEC. 2005

CHAS. HUDE A/S
33, H.C. Andersens Boulevard
DK-1780 Copenhagen V
Denmark

TR

Date of mailing (day/month/year) 24 November 2005 (24.11.2005)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 78516 UCK/TR	
International application No. PCT/EP2003/013873	International filing date (day/month/year) 08 December 2003 (08.12.2003)

1. The following indications appeared on record concerning:		
<input checked="" type="checkbox"/> the applicant	<input checked="" type="checkbox"/> the inventor	<input type="checkbox"/> the agent <input type="checkbox"/> the common representative
Name and Address SØRENSEN, Edith, Trøst 5 Danasvej DK-8700 Horsens Denmark	State of Nationality DK	State of Residence DK
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
<input type="checkbox"/> the person	<input type="checkbox"/> the name	<input checked="" type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence
Name and Address SØRENSEN, Edith, Trøst 12b, Solvej DK-8700 Horsens Denmark	State of Nationality DK	State of Residence DK
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to:		
<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned	
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned	
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Soumia SAADALLAH
Facsimile No. (41-22) 338.70.80	Telephone No. (41-22) 338 8421

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE
COMMUNICATION OF THE INTERNATIONAL
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

CHAS. HUDE A/S
33, H.C. Andersens Boulevard
DK-1780 Copenhagen V
DANEMARK

Search no. PA	J.nr. 78 516	Ing. 1780
- 4 JUL 2005		
AS 400 COP/57	Til livret 57	

Date of mailing (day/month/year) 30 June 2005 (30.06.2005)		IMPORTANT NOTICE	
Applicant's or agent's file reference 78516 UCK/TR			
International application No. PCT/EP2003/013873	International filing date (day/month/year) 08 December 2003 (08.12.2003)	Priority date (day/month/year)	
Applicant CADBURY SCHWEPPE PLC et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this notice:

AU, AZ, BY, CH, CN, CO, DZ, EP, HU, KG, KP, KR, MD, MK, MZ, RU, SY, TM, US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE, AG, AL, AM, AP, AT, BA, BB, BG, BR, BW, BZ, CA, CR, CU, CZ, DE, DK, DM, EA, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, ID, IL, IN, IS, JP, KE, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MG, MN, MW, MX, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, SC, SD, SE, SG, SK, SL, TJ, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this notice is a copy of the international application as published by the International Bureau on 30 June 2005 (30.06.2005) under No. WO 2005/058263

4. **TIME LIMITS** for filing a demand for international preliminary examination and for entry into the national phase

The applicable time limit for entering the national phase will, subject to what is said in the following paragraph, be **30 MONTHS** from the priority date, not only in respect of any elected Office if a demand for international preliminary examination is filed before the expiration of 19 months from the priority date, but also in respect of any designated Office, in the absence of filing of such demand, where Article 22(1) as modified with effect from 1 April 2002 applies in respect of that designated Office. For further details, see *PCT Gazette* No. 44/2001 of 1 November 2001, pages 19926, 19932 and 19934, as well as the *PCT Newsletter*, October and November 2001 and February 2002 issues.

In practice, time limits other than the 30-month time limit will continue to apply, for various periods of time, in respect of certain designated or elected Offices. For regular updates on the applicable time limits (20, 21, 30 or 31 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at <http://www.wipo.int/pct/en/index.html>

For filing a demand for international preliminary examination, see the *PCT Applicant's Guide*, Volume I/A, Chapter IX. Only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination (at present, all PCT Contracting States are bound by Chapter II)

It is the applicant's sole responsibility to monitor all these time limits

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yolaine Cussac
Facsimile No. +41 22 740 14 35	Facsimile No. +41 22 338 70 80

From the INTERNATIONAL BUREAU

PCTINFORMATION CONCERNING ELECTED
OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)

To:

CHAS. HUDE A/S
33, H.C. Andersens Boulevard
DK-1780 Copenhagen
DANEMARK

78516	UCK
09 AUG. 2005	
AS 400	To: H. 10

Date of mailing (day/month/year) 04 August 2005 (04.08.2005)		Applicant's or agent's file reference 78516 UCK/TR		IMPORTANT INFORMATION	
International application No. PCT/EP2003/013873	International filing date (day/month/year) 08 December 2003 (08.12.2003)	Priority date (day/month/year)			
Applicant CADBURY SCHWEPPE PLC et al					

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

EP: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR
National: BG, CA, CN, CZ, DE, JP, KP, KR, MN, NO, PL, RO, RU, SK, US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

AP: BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW
EA: AM, AZ, BY, KG, KZ, MD, RU, TJ, TM
OA: BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG
National: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BR, BW, BY, BZ, CH, CO, CR, CU, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MW, MX, MZ, NI, NZ, OM, PG, PH, PT, SC, SD, SE, SG, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW

3. The applicant is reminded that he must enter the "national phase" before the expiration of 30 months from the priority date before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing, if prescribed, a translation of the international application (Article 39(1) (a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3) (b) and Rule 74.1)

Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide

The entry into European regional phase is postponed until 31 months from the priority date for all States designated for the purposes of obtaining a European patent

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yolaine Cussac
Facsimile No. +41 22 740 14 35	Facsimile No. +41 22 338 70 80

WRITTEN OPINION

International application No. PCT/EP2003/013873

I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-22 as originally filed

Claims, Numbers

1-22 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

WRITTEN OPINIONInternational application No. **PCT/EP2003/013873**

Novelty (N)	Claims	1-7 (no); 17-22 (yes)
Inventive step (IS)	Claims	1-22 (no)
Industrial applicability (IA)	Claims	1-22 (yes)

2. Citations and explanations**see separate sheet**

Item V. Reasoned statement

1. Reference is made to the following documents:

D1: US2003/0072841 (RAHAIAH J ET AL) 17 April 2003 (2003-04-17)
D2: US-A-4 400 372 (KLEBER CARL J ET AL) 23 August 1983 (1983-08-23)
D3: GB-A-2 348 370 (HODGES GERWYN TUDOR) 4 October 2000 (2000-10-04)
D4: WO97/11675 (COLGATE-PALMOLIVE COMPANY) 3 April 1997 (1997-04-03)
(document attached) - i lommer

2. INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

2.2 Chewing gum compositions comprising calcium pyrophosphate are well known in the art (D1: paragraph (0059); D2: column 17, lines 1-40; D3: claims 1 and 2). The proportions of claim 1 are also known: for instance D1 discloses chewing gums comprising 1-70% of abrasive polishing materials as calcium pyrophosphate. The chewing gum of D1 also contains more than 75% of polybutene, thus the content of solid materials of such composition also falls within the claimed ranges (see paragraph (0024)). Accordingly, claim 1 can not be considered novel over D1.

3. INDEPENDENT CLAIM 17

3.1 Both D1 and D2, which are independently considered to represent the most relevant state of the art, disclose the use of calcium pyrophosphate as abrasive material in chewing gums or confectionery compositions (D1: paragraph (0059) and D2: column 17, lines 27-29).

3.2 From this, the subject-matter of independent claim 17 differs in that the compositions are used to whiten tooth. The subject-matter of claim 17 is therefore novel (Art. 33(2) PCT).

3.3 The problem to be solved by claim 17 may be regarded as a new use of such

compositions. The solution to the problem is to use them as tooth whiteners.

- 3.4 The subject-matter of claim 17 can not be considered inventive: It is well known in the art that abrasive are incorporated into oral compositions to remove stains and discolouring pigments that are found on the teeth and that cause undesired discolouration. Thus, abrasives, and in particular calcium pyrophosphate are known to whiten the teeth (see D6: page 2, lines 34-35, page 3, lines 1-5 and page 4, third paragraph). For the skilled person, it would be obvious to use the compositions of D1 or D2 comprising abrasives such as calcium pyrophosphate in order to whiten tooth surfaces. As a consequence it is considered that claim 17 does not fulfill the requirements of Article 33(3) PCT regarding inventive step.
- 4 Since the subject-matter of independent claim 20 corresponds to the subject-matter of claim 17, the same reasoning as given for claim 17 will apply *mutatis mutandis*.
- 5 DEPENDENT CLAIMS 2-16, 18-19, 21-22.
- 5.1 Dependent claims 2-16, 18-19, 21-22 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect to novelty and/or inventive step (Article 33(2) and (3) PCT).

CHAS. HUDE

Chas. Hude A/S
H.C. Andersens Boulevard 33
DK-1780 Copenhagen V

Phone +45 33 19 34 00
Fax +45 33 19 35 00

www.chashude.com
chashude@chashude.dk

The European Patent Office
International Preliminary Examining Authority
Erhardtstrasse 27
D-80331 Munich

Via facsimile, confirmation copy via courier

27 January 2006

COPY

Dear Sirs

International patent application No EP/03/13873
Applicant: Cadbury Schweppes PLC
Our ref: 78516 MBE/TR

In response to the Written Opinion pursuant to Rule 66 (PCT) of 28 October 2005 in the above application, I hereby submit the Applicant's reply pursuant to rule 66.3. (PCT).

Prior art:

In reply to the prior art cited in the Written Opinion, please find below the Applicant's comments thereto.

D1 (US 2003/072841) relates to "chewing gum" and "confectionary" comprising a polybutene with a molecular weight of 300 to about 3000. The objective problem solved hereby relates to the inhibition of the build-up of plaque and other debris on teeth.

In paragraph 59, it is stated that the compositions may additionally include an abrasive. Specific examples include calcium pyrophosphate and calcium carbonate, among numerous other suitable abrasive materials. Mixtures of abrasives may also be used. The abrasive in the chewing gum compositions is generally present from about 1% to about 70%, in one embodiment from about 5% to about 50%, by weight of the chewing gum or confection composition.

D1 does not comprise examples of chewing gums comprising calcium pyrophosphate nor is it indicated anywhere herein that calcium pyrophosphate is especially useful in chewing

gums or confectionary compositions, as compared to the use of other known abrasives, let alone as a whitening agent.

D2 (US 4,400,372) discloses a chewing gum comprising calcined kaolin particles. The gum is suited for dental cleaning and dental polishing.

Column 17, lines 1–40, reports the effect on abrasion of calcination temperatures of the kaolin particles using calcium pyrophosphate particles as reference. The effect on abrasion is determined according to the American Dental Association tooth brushing abrasion method. This method involves brushing radioactive enamel or dentin specimens with slurries of abrasive (cf. column 18, lines 40-44).

D2 does not anywhere disclose chewing gums or confectionary containing calcium pyrophosphate.

D3 (GB-A-2348370) relates to a “tooth “N” gum chewing gum” containing magnesium trisilicate as a polishing agent. The tooth “N” gum chewing gum may further contain calcium pyrophosphate as an effective anti plaque, anti tartar agent. It is stated that calcium pyrophosphate “kills the plaque bacteria and helps break up tartar formation” (p. 2 lines 38-39). Accordingly, the tooth “N” gum chewing gum of the invention may contain calcium pyrophosphate (Fig. 1, ref. 3) or may not contain calcium pyrophosphate (refs 1, 2 or 4). In any event, D3 fails to provide information as to suitable concentrations for calcium pyrophosphate. Thus, the application does not comprise an example of a chewing gum comprising calcium pyrophosphate, but merely comprises a suggestion to use calcium pyrophosphate as an anti-plaque agent in chewing gum compositions. Nowhere in D3 is it indicated that calcium pyrophosphate is especially useful as an abrasive, let alone as a whitening agent, in chewing gum or confectionary compositions.

D4 (WO97/11675) relates to peroxide containing dentifrice preparations for whitening human teeth. The preparations according to the invention may contain abrasive compounds, among which calcium pyrophosphate is mentioned, in an amount of between 10% and 50%, preferably between 20% to about 40%.

D4 does not disclose chewing gums or confectionary containing calcium pyrophosphate.

Novelty of new claims 1 - 16

The Applicant considers the invention, as defined by the claims on file, to meet the criteria of Article 33(1) PCT and to be new in the sense of Article 33(2) PCT. This is substantiated below.

The present invention differs from the prior art in a) the selection of Calcium Pyrophosphate as a whitening agent and b) in a selected amount of between 0.5%–9%. This selection was surprisingly found to confer a superior whitening effect to chewing gum compositions as compared to other conventional abrasive agents.

Thus, the present invention may be regarded as a "selection invention", wherein the selection of a particular abrasive agent in a particular amount has the surprising effect that it is suited as a whitening agent in a selected oral composition.

Common practice at e.g. the European Patent Office (EPO) is to allow so-called "selection inventions" directed to the selection of a specific sub-range from a known broad range or to a specific combination of concrete elements from two broad lists of known concrete elements (the "two-lists principle"). This is implemented in the Guidelines for Examination, Part C IV 7.7 which state:

"In determining the novelty of a selection, it has to be decided, whether the selected elements are disclosed in an individualised (concrete) form in the prior art (see T 12/81, OJ 8/1982, 296). A selection from a single list of specifically disclosed elements does not confer novelty. However, if a selection from two or more lists of a certain length has to be made in order to arrive at a specific combination of features then the resulting combination of features, not specifically disclosed in the prior art, confers novelty (the "two-lists principle")."

As elaborated above, the prior art cited fails to provide specific examples of chewing gum compositions comprising calcium pyrophosphate. In the present case, the closest prior art, D1, suggests using an abrasive material and discloses a myriad of concrete possibilities. Furthermore, D1 discloses to use said abrasive material in an amount of between 1%–70%,

and, in one embodiment, from about 5% to about 50%, by weight of the chewing gum or confection composition.

The selected amount of calcium pyrophosphate according to the present invention could be considered the selection of a specific sub-range from a known broad range and thus, taken alone, confers novelty to the invention according to the common practice at the EPO. However, the suited amount of abrasive disclosed in D1 could, in the broadest definition, be considered as disclosing all the concrete percent values between 1% and 70%. Thus, the selection of calcium pyrophosphate as well as the selection of the concrete values of 0.5%-9%, should confer novelty to the present claims according to the "two-lists principle" at the EPO.

According to the PCT Applicants Guide, novelty is to be acknowledged when the prior art does not anticipate the disclosed invention. As stated above, the Applicant is of the opinion that nothing in the prior art anticipates the present invention and that the invention is to be considered novel before e.g. the EPO. As case law similar to the practice at the EPO exists among a number of PCT contracting states and the invention is neither specifically disclosed nor hinted or anticipated by the prior art, the application is to be considered novel in the sense of article 33(2) PCT.

Inventive step of new claims 1 - 16

The applicant considers the invention, as defined by the claims on file, to meet the criteria of Article 33(1) PCT and to involve an inventive step in the sense of Article 33(2) PCT. This is substantiated below.

The present invention is regarded as a "selection invention", wherein the selection of a particular abrasive agent in a particular amount has the surprising effect that it is suited as a whitening agent.

The technical problem solved by the present invention is to provide an improved chewing gum composition for whitening teeth. The solution was the formulation of a chewing gum composition comprising the abrasive agent calcium pyrophosphate, which was surprisingly found to have a significantly better whitening effect compared to other commonly used abrasives.

This effect is evident from the application as filed, as seen in e.g. table 4 and table 5 on page 20. However, in order to further substantiate this surprising effect, the Applicant is currently in the process of providing new supplementary experimental evidence, which will be submitted as soon as possible.

Although Calcium Pyrophosphate is used as an abrasive agent in e.g. toothpastes and mentioned as such in the prior art documents D1–D4 along with numerous other common abrasive agents, no hints can be found in the prior art as to any surprising beneficial effect of calcium pyrophosphate as a whitening agent superior to other abrasive agents.

The prior art referred to above fails to produce a single example of a chewing gum composition comprising calcium pyrophosphate. Although calcium pyrophosphate is proposed as an abrasive agent in oral formulations and mentioned as such along with numerous other common abrasives in some of the cited prior art documents, no hints can be found in the prior art as to any surprising beneficial effect of calcium pyrophosphate as a whitening agent, superior to other abrasive agents. Even more specifically, the skilled person would not find any motivated guidance or directions as to the superior effect of the specific choice of calcium pyrophosphate in a chewing gum composition.

D1-D4 alone or in combination fail to provide the skilled person with more than the ubiquitous and quite conventional phrasing of the possibility of using, in dental compositions, one or more of a range of known abrasive materials in an amount of between 1-70%. Thus, D1-D4 alone or in combination fail to direct the skilled person to the solution of the problem of tooth whitening by using calcium pyrophosphate in an amount of between 0.5%-9% in a chewing gum composition as disclosed in the present invention.

The Applicant is of the opinion that the subject-matter of the claims 1-16 involves an inventive step in the sense of Article 33(2) PCT.

Inventive step of new claims 17 - 22

The PCT Examiner is of the opinion that the present claims 17 – 22 are novel in that the compositions according to the present invention are used for whitening teeth. The Applicant agrees, but finds it appropriate to add that neither D1 nor D2 contain examples of composi-

tions according to the present invention and accordingly any uses of such a composition according to the present invention are as such novel.

Furthermore, the Applicant finds it appropriate to point out that although abrasion of teeth surfaces may remove a minor amount of colouring pigment and thus in some way confer a whitening effect (as suggested in D4, p. 3, lines 1-3), an abrasion effect is in no way a guarantee of or synonymous to a whitening effect. The experimental assessments of whitening and abrasion are by no means identical and whitening and abrasion are two different effects. Thus, a whitening agent and an abrasive agent cannot substitute one another. This is also seen in D1, where whitening agents are described in paragraph 0039, and abrasive agents in paragraph 0059, and further in D4 where it is stated that "A drawback to the use of whitening products which are formulated without abrasives is that, in addition to the stability problem, the products are not effective in stain removal" (p. 2, lines 32-34). The use of an abrasive which in it self may act as both an abrasive and a whitening agent is therefore by no means disclosed nor anticipated by the prior art.

By showing that the use of calcium pyrophosphate results in significantly improved whitening, as compared to a potential whitening effect of other known abrasives, it is substantiated that calcium pyrophosphate has a whitening effect. This is both new and surprising. Therefore, the use of calcium pyrophosphate for whitening of teeth in chewing gum compositions most certainly does confer an inventive step within the meaning of Art 33 (3) PCT. Accordingly, it is respectfully submitted that the present claims are inventive

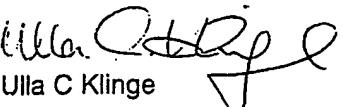
In light of the above, the Examiner is respectfully requested to reconsider his opinion and issue an International Preliminary Examination Report acknowledging the patentability of the present invention.

In the event that the Examiner has any questions concerning this application, the Examiner is hereby invited to contact the undersigned by telephone on the above number.

Should the Examiner be so minded as to issue an Examination Report rejecting the patentability of this application, the Representative of the Applicant hereby respectfully requests a telephone interview with the Examiner pursuant to rule 66.6 (PCT).

CHAS.HUDE

Yours faithfully


Ulla C Klinge
Representative of the Applicant

Enc: Form 1038

CHAS.HUDE

COPY

The European Patent Office
International preliminary examining authority
Erhardtstrasse 27
D-80331 Munich

Chas. Hude A/S
H.C. Andersens Boulevard 33
DK-1780 Copenhagen V

Phone +45 33 19 34 00
Fax +45 33 19 35 00

www.chashude.com
chashude@chashude.dk

To be delivered to Ms Sierra Gonzalez,
Authorised Officer

24 March 2006

Via facsimile

Dear Ms Gonzalez

International patent application No PCT/ EP/2003/13873
Applicant: Cadbury Schweppes PLC
International classification: IPC A61K7/16
Our ref.: 78516 MBE/TR

With reference to my reply to the Written Opinion pursuant to Rule 66.3 (PCT) of 27 January 2006 and our pleasant telephone conversation of 3 February 2006, I hereby submit additional experimental evidence supporting the patentability of the invention described in the above application.

The attached summary table lists the results of a comparative test on the whitening effect (removal of artificial stains from pieces of enamel) of chewing gum compositions comprising equimolar amounts of calcium pyrophosphate and calcium carbonate, respectively.

The compositions of the chewing gums were as follows:

Gum A contained 0.02 mmol calcium carbonate/g chewing gum (corresponding to 0.2% by weight of calcium carbonate).

Gum B contained 0.02 mmol calcium pyrophosphate/g chewing gum (corresponding to 0.5% by weight of calcium pyrophosphate).

Gum C contained 0.35 mmol calcium carbonate/g chewing gum (corresponding to 3.6% by weight of calcium carbonate).

Gum D contained 0.35 mmol calcium pyrophosphate/g chewing gum (corresponding to 9.0% by weight of calcium pyrophosphate).

Results

As can be seen when comparing composition C with composition D comprising equimolar high amounts of abrasive material, a statistically significantly improved whitening effect was obtained using chewing gums containing calcium pyrophosphate at all measured times.

The same tendency in effect is seen when comparing composition A with composition B comprising equimolar low amounts of abrasive material. Although the whitening effect of calcium pyrophosphate-containing gums was marginally lower at the first point in time (20 minutes), the improved whitening effect is seen already at the second point in time (40 minutes) and a statistically significantly improved whitening effect was seen at the last measured point in time (120 minutes).

Comparing composition A with C, and B with D, respectively, it is evident that increasing the amount of abrasive material results in an increasing whitening effect.

When comparing composition B containing low amounts of calcium pyrophosphate (0.02 mmol/g or 0.5%) with C containing high amounts of calcium carbonate (0.35 mmol/g or 3.6%), it appears that although a more efficient whitening is obtained using composition C, the effects are not statistically different, neither initially (20 minutes), nor at the end of the study. Thus, composition B results in a whitening effect comparable to composition C, even though composition B comprises abrasive material at concentrations that are 18 times lower (mole) or 7 times lower (weight percent).

Conclusion

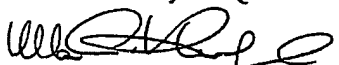
In conclusion, the experimental evidence confirms the beneficial effects of chewing gum compositions comprising calcium pyrophosphate on the whitening of teeth disclosed in the above mentioned application. Calcium pyrophosphate is shown to be statistically significantly more effective in whitening compared to the conventional abrasive calcium carbonate

CHAS. HUDE

at equimolar concentrations. Even at concentrations of calcium pyrophosphate far lower than calcium carbonate, comparable effects were observed.

The presently submitted additional experimental evidence is to be viewed only as such. For facts and arguments in favour of novelty and inventive step in view of the cited prior art, I refer to the above mentioned reply to the written opinion.

Yours faithfully



Ulla C. Klinge
Representative of the Applicant

Enc: Summary Table
Form 1038
List of Additional Representatives

SUMMARY TABLE

TOTAL CHANGE (ΔE) IN EXTRINSIC DENTAL STAIN
BY CHEWING GUMS A - D

Chewing Gum		Total Change (ΔE) in Extrinsic Stain Score†		
Group	Code	20 Min	60 Min	120 min
1	A	1.48 ± 0.72^A	1.95 ± 0.75^A	2.65 ± 0.65^A
2	B	1.33 ± 0.60^A	3.16 ± 0.81^A	$5.40 \pm 1.32^{B,C}$
3	C	2.43 ± 0.93^A	5.57 ± 1.24^B	6.64 ± 0.93^C
4	D	4.12 ± 1.82^B	9.05 ± 2.46^C	11.39 ± 2.66^D

† Mean \pm standard deviation, n = 8. Test gum mechanically chewed over consecutive 20-minute. Gum and saliva changed every 20 minutes. Values in the same column with the same superscript letter are not statistically different, while those with different superscript letters are different at $p < 0.05$ based on ANOVA.

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:
 IPEA/ EPO _____

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
 The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

For International Preliminary Examining Authority use only	
Identification of IPEA	Date of receipt of DEMAND
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION	
Applicant's or agent's file reference 78516 UCK/SJ	
International application No EP/03/13873	International filing date (day/month/year) 08 December 2003 (08122003)
(Earliest) Priority date (day/month/year) -	
Title of invention A Solid Oral Tooth Whitening Composition	
Box No. II APPLICANT(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
Cadbury Schweppes PLC 25 Berkeley Square London W1J 6HB GB	Telephone No. +44 20 74 09 13 13
	Facsimile No. +44 20 78 30 52 00
	Teleprinter No. -
	Applicant's registration No. with the Office -
State (that is, country) of nationality: GB	State (that is, country) of residence: GB
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
SØRENSEN, Edith Trøst 5 Danasvej DK-8700 Horsens Denmark	
State (that is, country) of nationality: DK	State (that is, country) of residence: DK
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
State (that is, country) of nationality:	State (that is, country) of residence:
<input type="checkbox"/> Further applicants are indicated on a continuation sheet	

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is ☒ agent ☐ common representative
and ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.
☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.
☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier

Name and address: (Family name followed by given name. for a legal entity, full official designation)
(The address must include postal code and name of country)

CHAS. HUDE A/S
H.C. Andersens Boulevard 33
DK-1780 Copenhagen V
Denmark

Telephone No.

+45 33 15 45 14

Facsimile No

+45 33 15 45 35

Teleprinter No

-

Agent's registration No with the Office

-

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments:*

1 The applicant wishes the international preliminary examination to start on the basis of:

☒ the international application as originally filed
the description ☒ as originally filed
☐ as amended under Article 34

the claims ☒ as originally filed
☐ as amended under Article 19 (together with any accompanying statement)
☐ as amended under Article 34

the drawings ☒ as originally filed
☐ as amended under Article 34

2 ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3 ☐ Where the IPEA wishes to start the international preliminary examination at the same time as the international search in accordance with Rule 69.1(b), the applicant requests the IPEA to postpone the start of the international preliminary examination until the expiration of the applicable time limit under Rule 69.1(d)

4 ☐ The applicant expressly wishes the international preliminary examination to start earlier than at the expiration of the applicable time limit under Rule 54bis.1(a)

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

☒ which is the language in which the international application was filed.
☐ which is the language of a translation furnished for the purposes of international search.
☐ which is the language of publication of the international application
☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination

Box No. V ELECTION OF STATES

The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the PCT

See Notes to the demand form

Sheet No . 3

International application No
EP/03/13873

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | | | |
|----|---|---|---|--------|
| 1 | translation of international application | : | | sheets |
| 2 | amendments under Article 34 | : | | sheets |
| 3 | copy (or, where required, translation) of amendments under Article 19 | : | | sheets |
| 4 | copy (or, where required, translation) of statement under Article 19 | : | | sheets |
| 5 | letter | : | 1 | sheets |
| 6. | other (specify) copy of int. search report | : | 5 | sheets |

For International Preliminary
Examining Authority use only

received

not received

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

The demand is also accompanied by the item(s) marked below:

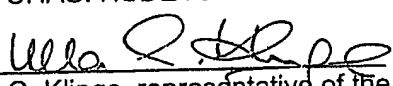
- 1 ☒ fee calculation sheet
- 2 ☐ original separate power of attorney
- 3 ☐ original general power of attorney
- 4 ☐ copy of general power of attorney; reference number, if any:

- 5 ☐ statement explaining lack of signature
- 6 ☐ sequence listing in electronic form
- 7 ☐ tables in electronic form related to a sequence listing
- 8 ☐ other (specify):

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand)

CHAS. HUDE A/S


 Ulla C. Klinge, representative of the applicants

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply
- ☐ The applicant has been informed accordingly.
- 4 ☐ The date of receipt of the demand is WITHIN the time limit of 19 months from the priority date as extended by virtue of Rule 80.5
- 5 ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

6 ☐ The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54bis.1(a) and item 7 or 8, below, does not apply7 ☐ The date of receipt of the demand is WITHIN the time limit under Rule 54bis.1(a) as extended by virtue of Rule 80.5.8 ☐ Although the date of receipt of the demand is after the expiration of the time limit under Rule 54bis.1(a), the delay in arrival is EXCUSED pursuant to Rule 82

For International Bureau use only

Demand received from IPEA on:

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To: CHAS. HUDE AS 33, H.C. Andersens Boulevard DK-1780 Copenhagen V DANEMARK		WRITTEN OPINION (PCT Rule 66)															
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; text-align: center;">Sagstype AA</td> <td style="width: 25%; text-align: center;">J. nr. 78516</td> <td style="width: 25%; text-align: center;">Ing. UCK</td> <td style="width: 25%;"></td> </tr> <tr> <td colspan="4" style="text-align: center; padding: 10px;">28 OKT. 2005</td> </tr> <tr> <td style="text-align: center;">AS 400 TR</td> <td colspan="3" style="text-align: center;">UCK</td> </tr> </table>		Sagstype AA	J. nr. 78516	Ing. UCK		28 OKT. 2005				AS 400 TR	UCK			<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Date of mailing (day/month/year)</td> <td style="width: 50%; text-align: center;">28.10.2005</td> </tr> </table>		Date of mailing (day/month/year)	28.10.2005
Sagstype AA	J. nr. 78516	Ing. UCK															
28 OKT. 2005																	
AS 400 TR	UCK																
Date of mailing (day/month/year)	28.10.2005																
Applicant's or agent's file reference 78516 UCK/TR		REPLY DUE within 3 month(s) from the above date of mailing															
International application No. PCT/EP2003/013873	International filing date (day/month/year) 08.12.2003	Priority date (day/month/year) 08.12.2003															
International Patent Classification (IPC) or both national classification and IPC A61K7/16																	
Applicant CADBURY SCHWEPPE PLC et al.																	

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:

I	<input checked="" type="checkbox"/>	Basis of the opinion
II	<input type="checkbox"/>	Priority
III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/>	Lack of unity of invention
V	<input checked="" type="checkbox"/>	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/>	Certain documents cited
VII	<input type="checkbox"/>	Certain defects in the international application
VIII	<input type="checkbox"/>	Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
 For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
 For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **08.04.2006**

Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 </div> </div>	Authorized Officer Sierra Gonzalez, M - 3751 Formalities officer (incl. extension of time limits) Cherqui, E Telephone No. +31 70 340-2643
---	--